



MEDICAL SCHOOL
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The Honorable Fred Upton, Chairman
The Honorable Diana DeGette
Energy and Commerce Committee
United State House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton and Congresswoman DeGette:

The University of Michigan Medical School and Health System thanks you and your Committee members for your leadership in advancing the 21st Century Cures initiative. We are especially pleased to support the provision adding 'research' to the definition of 'health care operations'. This will allow HIPAA-protected yet unprecedented assured access to data on how care in all settings affects the outcomes and care needs of all patient types. Today, this data is largely wasted by unworkable requirements to obtain individual consent for every single use of clinical records for research purposes.

This change is long overdue. Efficient access to records by researchers while maintaining patient privacy will unlock a vast amount of information on care delivered in different places to different patients, including smaller clinical settings where much care across the nation is delivered today. These latter data include people with multiple comorbidities who are increasingly common as a result of our aging population. Academic clinical trial sites often exclude data and patients from smaller clinical sites hindering the progress of improving the health of our nation.

The evidence we can gain from access to such rich data sources touches all levels and kinds of biomedical and health research from supporting hypothesis generation for translational research to making clinical care process improvements and using such information relating to access, quality, and safety of care for public health advancements, including development of better measures for evaluation and continuous improvement.

Similarly, we support the language that seeks to remove the duplicative research reviews by both the FDA and OHRP for some clinical trial research. This duplication is confusing at the minimum, plus the capacity of the FDA to perform inspections puts them in the best position to assure appropriate patient protections.

Thank you for your important leadership. We wish to assure the Committee that HIPAA will not be weakened by this legislation which is certain to improve the nation's capacity to deliver better care at lower cost. Please contact me at woolli@umich.edu or 734-764-8175 should you wish to follow up on these comments.

Sincerely,

James O. Woolliscroft, MD
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cc: Rick Bossard